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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,320	02/15/2001	D. Wade Walke	LEX-0137-USA	3185

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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/17/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,320	WALKE ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5 and 11-14* is/are pending in the application.

4a) Of the above claim(s) *5,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 4-5 and 11-14 are pending.

Applicant's cancellation of claims 1-3, 6-10 and addition of claims 11-14 in Paper No. 13, filed on 9/30/2002 is acknowledged.

It is noted that newly added claims 13-14 are drawn to the non-elected invention of claim 5. As such, new claims 13-14 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

This application contains claims 5 and 13-14 drawn to an invention non-elected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claim 11 is objected to because of the following informalities: it is suggested that the term "a nucleic acid" be replaced with "the nucleic acid" since the nucleic acid is defined in claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4, 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

4. Claims 4, 11 and 12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. These rejections, which were discussed in previous Office Actions Paper No. 11, mailed on 5/22/2001, were applied to claim 4 and are now applied to new claims 11-12 for the reasons of record.

6. Applicants have extensively argue that the polynucleotides of the instant invention have substantial, credible, specific and well-established utility. Applicants assert that the function of the polypeptide of SEQ ID NO: 4 is that of a NEK1 kinase. Furthermore, Applicants argue that the Examiner requires experimental data and that the need for some experimentation does not render the claimed invention unpatentable. It is Applicant's opinion that the requirements under the law for obtaining a patent are not the same as those for FDA's approval.

In addition, Applicants argue that an additional "substantial" utility for the claimed polynucleotides is in the manufacture of DNA chips as evidenced by hundreds of issued patents. Applicants argue that the present invention describes a metalloprotease and that the present nucleotide sequences clearly encode a human kinase (page 6, lines 1-4 of the Response). Since the present nucleotides are specific markers of the human genome, one can use them in the discovery of drugs or in screening for gene expression. Applicants further remind the Examiner that only a minor percentage of the genome encodes exons and therefore the practical scientific

value of the disclosed polynucleotide is readily apparent. Applicants direct the Examiner's attention to an article by Venter et al. which further supports Applicant's contention of how valuable the claimed polynucleotides are. Moreover, Applicants further assert that since one of skill in the art and investors readily recognize the economic value of genomic data, the claimed nucleotides must have substantial, credible and well-established utility.

As evidence of a credible function, Applicants have submitted an alignment of the amino acid sequence of SEQ ID NO: 4 against a polypeptide which has been assumed to correspond to EMBL accession number Q96PY6 (Nagase et al. DNA Res. 8(4):179-187, 2001), since the accession number provided by Applicants could not be found in publicly available databases. According to Applicant's opinion, the high homology between the polypeptide of the instant invention and that of Nagase et al. should be sufficient to show that Applicant's invention encodes a NEK1 kinase. In addition, Applicants have presented abstracts from articles by Letwin et al. (EMBO J 11(10):3521-3531, 1992) and Upadhya et al. (Proc Natl Acad Sci 97(1):217-221, 2000) to support the argument that NEK1 is known in the art and that mutations in NEK1 can result in kidney disease in mice. It is Applicant's opinion that the PTO has issued several patents on polynucleotides that have not been directly associated with the function of the polypeptide they encode. Finally, Applicants direct the Examiner's attention to several patents where there are no working examples or examples of real-world utilities.

7. It is noted that the specification does not disclose the function of the polypeptide encoded by SEQ ID NO: 4 as that of a NEK1 kinase as asserted in the Response filed on 9/30/2002.

8. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. The Examiner acknowledges that NEK1 is known in mice and that

mutations in NEK1 in mice have been associated with kidney disease. In regard to Applicant's assertion of function, it is noted that the function of the polypeptide of Nagase et al. has been predicted based on sequence homology (Nagase et al., DNA Res. 8(4):179-187, 2001; Abstract), therefore there is no clear and convincing evidence that in fact the polypeptide of Nagase et al. is indeed a NEK1 kinase. The state of the art teaches the unpredictability of assigning function based on sequence homology and that small amino acid changes can drastically change the function of a polypeptide. Bork (Genome Research, 10:398-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. In the absence of information as to the specificity or the substrate of the alleged kinase or the critical structural elements which are required to display NEK1 kinase activity, one of skill in the art cannot reasonably conclude that the claimed polynucleotide encodes a NEK1 kinase. At best, one of skill in the art can only conclude that the polynucleotides of SEQ ID NO: 4 and Nagase et al. are highly homologous.

In regard to requirements of experimental data, further experimentation and requirements under the law in regard to patentability, the Examiner agrees that (1) experimental data is not a

requirement for patentability, (2) some experimentation does not render an invention unpatentable, and (3) FDA's approval is not a requirement for patentability. However, in the instant case, in view of the fact that one cannot reasonably determine if the claimed polynucleotide encodes a kinase, the type of kinase, specificity and substrate, one would require further research to identify or reasonably confirm a "real world" context of use. Therefore, as discussed in previous Office Action Paper No. 11, the claimed utility is not a substantial utility.

In regard to arguments that the instant polynucleotide can be used in DNA chips, drug discovery, or to measure gene expression, those uses are not "substantial" in view of the fact that one would require further research to identify or confirm a "real world" context of use. One would need some information as to how the claimed polynucleotide, the product it encodes, its overexpression or underexpression, correlate with abnormalities or disease to be used in drug discovery. Furthermore, it is unclear from Applicant's own arguments, which is the asserted function since the function of the polypeptide encoded by the claimed polynucleotide has been stated as that of a metalloprotease and a NEK1 kinase.

In regard to utility due to an increase in the economic value of the human genomic data, this use is not a specific utility in view of the fact that other polynucleotides would also contribute to the value of the human genomic data. In response to arguments that the PTO has issued several patents on polynucleotides which do not have a specific function associated with them or patents which lack real-world utility or working examples, Applicants are reminded that each application is examined on its own merits and that the instant application is being examined using the revised utility guidelines.

Conclusion

9. No claim is in condition for allowance.

10. Applicant's addition of new claims 11-12 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

12. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE

COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
December 13, 2002

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600